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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,379	12/09/2003	Daniel Zamanillo Castanedo	P03,0588	4441

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SCHIFF HARDIN, LLP
PATENT DEPARTMENT
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EXAMINER

HIRIYANNA, KELAGINAMANE T

ART UNIT	PAPER NUMBER
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1633

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,379	CASTANEDO ET AL.	
	Examiner	Art Unit	
	Kelaginamane T. Hirianna	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01/03/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 14-20 and 22-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 14-20 & 22-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some.* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on 01/03/2007 in response to office action mailed on 06/28/2006 has been acknowledged.

Claims 4, 7, 10, and 24 are cancelled.

Claims 1-3, 5-6, 8-9, 14-15, 17-18, 20-23, and 25-29 are amended.

Claim 30 is newly added.

Claims 1-3, 5-6, 8-9, 11-23, and 25-30 are pending and are examined in this office action.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action. All the affidavits filed by the applicant on 01/03/2007 in support of the instant invention have been duly considered.

Claim Rejections - 35 USC § 101

Claims 14-16 are rejected under 35 U.S.C. 101 because claim is drawn to non-statutory subject matter as follows:

Claims 14 and dependent claims are drawn to 'host cells'. When read broadly this encompasses live human beings as genetically engineered. It is PTO policy not to allow claims to humans (1077 O.G. 24 April 1987). The insertion of a phrase such as 'an isolated host cell', or 'cell of a non-human mammal' or 'excluding human organism' would overcome this rejection.

Claims 1-3, 5-6, 8 and 22-26 as written, do not sufficiently distinguish mutant mice as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the

absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "transgenic" in case of a live animal. See MPEP 2105.

Claim Rejections - 35 USC § 112

Claims 1-3, 5-6, 8, 17-19 and 22-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a mutant transgenic mouse whose genome comprises a disruption in endogenous gene coding for Sigma-1 receptor wherein a mouse homozygous for said Sigma-1 receptor gene disruption (-/-) completely lacks ability to express transcripts and translation products of said gene and exhibits a phenotype where in cell membranes lack the ability to bind pentazocine as compared wild type control mice, is not enabled for any other endogenous Sigma-1 receptor gene mutant mice exhibiting any other phenotypes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Since the specification fails to disclose any other transgenic mice with mutations of sigma receptor-1 gene and exhibiting phenotype, other than said gene disrupted mouse, it is not evident to one of skill in the art that all claimed mutations would result in a mutant phenotype equivalent to said gene disrupted mouse. Further, the same holds good for the isolated cells or tissues derived from claimed mutant transgenic mice. The applicant's disclosure does not enable one skilled in the art to practice the invention as claimed without further undue amount of experimentation, which requires the construction and characterization of any and/or all mouse mutants (deletions, missense, nonsense etc) of sigma receptor-1 gene. (in any nucleotide base of coding, non-coding and regulatory regions of the gene) and further because the art of transgenics is unpredictable with regard to broadly mutant mice as set forth in the previous office action of 06/28/2006. At issue, under the enablement requirement of 35 U.S.C.112, first paragraph is whether, given the Wands-factors, the experimentation was undue or unreasonable under the circumstances. "Experimentation must not require ingenuity beyond that to be expected of

one of ordinary skill in the art." See *Fields v. Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1970).

Claim Rejections - 35 USC § 103

Claims 9, 11-12, 21 and 29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Capecchi (U.S. Pat. No.5,464,764) in view of Seth et al., (2000, *Biochemical and Biophysical Research communications* 241: 535-540) as applied to above claims and as set forth in the office action mailed on 06/28/2006.

Response to Applicants arguments of 01/03/2007:

Applicant argues that the sigma-1 receptor gene targeting vector used in the instant invention for generating a null mice in the gene has been constructed in a specific way than in the prior art in combination can describes and further the method used for generating said mutant mice was different from the prior art methods. However, this is found not persuasive because the invention as instantly claimed do not reflect any specific nature of the construct or that of the method of sigma-1 gene targeting used, other than the conventional ones that is amply described in the art. Further specification does not emphasize any special rationale (away from the prior art practice) for the selected segments of the genome used for targeting said gene.

Claims 13 and 30 are allowable but are objected to because of their dependence on rejected claims.

Conclusion:

No claim allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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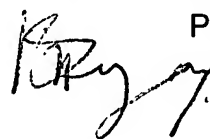
MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna* whose telephone number is (571) 272-3307. The examiner can normally be reached Monday through Friday from 9 AM-5PM. Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst *William N. Phillips* whose telephone number is 571 272-0548. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach*, may be reached at (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

Kelaginamane T. Hiriyanna

Patent Examiner

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SUMESH KAUSHAL, PH.D.
PRIMARY EXAMINER